

K073069

JAN 25 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site: VIASYS Respiratory Care Inc
1100 Bird Center Drive
Palm Springs, CA 92262

Contact: Tom Gutierrez (760) 778-7255 (phone); (760) 831-7181 (fax)

Summary Date: August 3,-2007

Device Trade Name: AVEA Ventilator

Device Common/Classification Name: Classification name: 868.5895 Continuous Ventilator, 73 CBK

Establishment Registration Number: 2021710

Device Class: Class II

Classification Panel: Anesthesiology

Predicate Device: The predicate devices are:

- Resironics NICO K982499
- Maquet Servo-I K022132
- Cosmo Plus 8000 K963380

Device Description: The AVEA is a servo-controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for neonatal through adult patients. Its graphical user interface module (UIM) has a flat panel color LCD with real time charting and digital monitoring capabilities, a touch screen for interaction, membrane keys and a dial for changing settings and operating parameters. It also has an internal gas delivery system with servo controlled active inhalation and exhalation functions. Using internal batteries this provides inter-hospital transport as well as back up capability due to loss of AC power. The AVEA may be configured as a conventional ventilator or non-invasive positive pressure ventilator (NPPV). It has been designed to function using commonly available accessories.

<u>Intended Use:</u>	The AVEA is intended to provide continuous respiratory support in an institutional health care environment (e.g. hospitals). It may be used on adult, pediatric, and neonatal patients. It should only be operated by properly trained clinical personnel, under the direction of a physician.
<u>Substantial Equivalence</u>	<p>The AVEA Ventilator is the same device as the AVEA Ventilator, which was cleared for market under 510(k) K013642 and K022674.</p> <p>Modifications to the AVEA Ventilator are associated with this submittal are as follows:</p> <ul style="list-style-type: none">• Capnometry monitor operation• Provisions for barometric pressure compensation operation <p>The modified AVEA Ventilator have the following similarities to those which previously received 510(k) concurrence:</p> <ul style="list-style-type: none">• have the same indicated use,• use the same ventilation operating principle,• incorporate the same basic ventilator design with the exception of modifications described in this submittal.• incorporate the same basic electronic control system• are manufactured and packaged utilizing the same basic processes. <ul style="list-style-type: none">• In summary, the AVEA Ventilator described in this submission is, in our opinion, substantially equivalent to the predicate device(s).
<u>Summary of Testing and Validation:</u>	Performance testing verified that the AVEA Ventilator meets its performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Mr. Tom Gutierrez P.E.
Regulatory Affairs Manager
VIASYS Respiratory Care Incorporated
1100 Bird Center Drive
Palm Springs, California 92262

Re: K073069
Trade/Device Name: AVEA Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 29, 2007
Received: October 30, 2007

Dear Mr. Gutierrez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

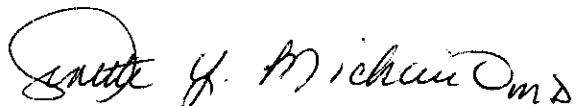
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): 1073069

Device Name: AVEA Ventilator

Indications for Use:

The AVEA is intended to provide continuous respiratory support in an institutional health care environment (e.g. hospitals). It may be used on adult, pediatric, and neonatal patients. It should only be operated by properly trained clinical personnel, under the direction of a physician.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)
M. M. M. M.

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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(Posted November 13, 2003)